In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: January 25, 2021

JEFFREY SCHAFER,	*	PUBLISHED
	*	
Petitioner,	*	No. 16-0593V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Causation-in-Fact; Influenza ("Flu") Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA").
	*	
Respondent.	*	
	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On May 19, 2016, Jeffrey Schafer ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that he suffered a right shoulder injury as

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

the result of an influenza ("flu") vaccination administered on October 15, 2014.[3] Amended ("Am.") Petition at 1 (ECF No. 37).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner provided preponderant evidence that the flu vaccine caused petitioner's right shoulder injuries, which satisfies his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

I. PROCEDURAL HISTORY

Petitioner filed his petition on May 19, 2016, alleging that he sustained right shoulder injuries caused by a flu vaccine administered on October 15, 2014. Petition at 1-2 (ECF No. 1); Am. Petition at 1-2. The early procedural history from May 2016 through August 2019 was set forth in the undersigned's Fact Ruling and will not be repeated here. See Order Denying Respondent's Motion to Dismiss and Fact Ruling on Six Month Requirement dated Aug. 28, 2019 ("Fact Ruling") dated Aug. 28, 2019, at 2-3 (ECF No. 57).

After the undersigned issued her Fact Ruling, the parties engaged in settlement discussions. Joint Status Report ("Rept."), filed Sept. 27, 2019 (ECF No. 58). Respondent was also ordered to file an amended Rule 4(c) Report. Order dated Nov. 19, 2019 (ECF No. 63). After respondent missed multiple deadlines to update the Court on the parties' progress towards informal resolution and to file an amended Rule 4(c) Report, the undersigned issued an order to show cause. Order to Show Cause dated Apr. 6, 2020 (ECF No. 71).

On April 7, 2020, respondent filed a response to the order to show cause and his amended Rule 4(c) Report. Respondent's Amended Rule 4(c) Report and Response to Order to Show Cause ("Resp. Am. Rept."), filed Apr. 7, 2020 (ECF No. 72). In his amended Report, respondent maintained that this case was not appropriate for compensation. Id. at 3. He also acknowledged that Shoulder Injury Related to Vaccine Administration ("SIRVA") was added as a Table claim for all vaccines effective for petitions filed on or after March 21, 2017, and thus, because petitioner filed before that date, he had to proceed on a causation-in-fact claim and was "not entitled to the presumption that he [had] proven a recognized injury by merely satisfying the Table criteria." Id. at 1 n.1, 6-7.

[3] The amended petition alleges petitioner received his flu vaccination on October 6, 2014. Am. Petition at 1. However, petitioner's vaccination record indicates that petitioner received the vaccine on October 15, 2014. Petitioner's Exhibit ("Pet. Ex.") 6. Both petitioner and respondent also state petitioner received the flu vaccine on October 15, 2014, and thus the date of vaccination is not in dispute. See Pet. Motion for Ruling on the Record ("Pet. Mot."), filed July 16, 2020, at 1 (ECF No. 80); Respondent's Response to Pet. Mot. ("Resp. Response"), filed Aug. 17, 2020, at 2 n.2 (ECF No. 81); see also Order Denying Respondent's Motion to Dismiss and Fact Ruling on Six Month Requirement dated Aug. 28, 2019 ("Fact Ruling") dated Aug. 28, 2019, at 1 n.3 (ECF No. 57).

On June 15, 2020, petitioner filed a status report indicating that settlement did not appear to be possible. Petitioner's ("Pet.") Status Rept., filed June 15, 2020 (ECF No. 77). Thereafter, the undersigned set a briefing schedule. Order dated June 16, 2020 (ECF No. 78).

On July 16, 2020, petitioner filed a motion for a ruling on the record and two affidavits. Pet. Motion for Ruling on the Record ("Pet. Mot."), filed July 16, 2020 (ECF No. 80); Pet. Exhibits ("Exs.") 13-14. Respondent filed his response on August 17, 2020. Resp. Response to Pet. Mot. ("Resp. Response"), filed Aug. 17, 2020 (ECF No. 81).

Petitioner filed an expert report from Dr. Marko Bodor on November 16, 2020. Pet. Ex. 15. Respondent filed a status report on January 19, 2021, stating "[r]espondent [did] not intend to file an expert report." Resp. Status Rept., filed Jan. 19, 2021 (ECF No. 90).

This matter is now ripe for adjudication.

II. FACTUAL HISTORY

The Fact Ruling set forth a summary of petitioner's medical records relative to his right shoulder. See Fact Ruling at 3-5. Those summaries will not be repeated here. In the Fact Ruling, the undersigned found petitioner established that he suffered the residual effects of his vaccine-related injury for at least six months as required by the Vaccine Act. Id. at 7.

After the Fact Ruling issued, petitioner filed two additional affidavits. See Pet. Exs. 13-14. Petitioner averred that "[a]lmost immediately after receiving the injection for the [flu] vaccination, [he] began to suffer pain in [his] right shoulder, making it difficult to move the shoulder and use [his] right arm." Pet. Ex. 13 at ¶ 6. Petitioner declared that he had no right shoulder injury prior to his October 2014 vaccination. Pet. Ex. 14 at ¶ 3. He tried to manage the pain himself for about six weeks before he saw a physician who referred him to physical therapy. Pet. Ex. 13 at ¶¶ 7-8. Due to the injury, he was unable to continue to work as a painter. Id. at ¶ 9.

Petitioner also explained that since his October 2014 flu vaccination, "[his] right shoulder has never been completely pain free," but has "hurt less" over the years and "[he] ha[s] learned what activities to avoid." Pet. Ex. 14 at ¶ 6. He stated that his right shoulder hurts when he lifts items over his head, especially when they are heavy. Id. at ¶ 7. His shoulder also hurts when he sleeps on his right side. Id. He takes ibuprofen for the pain. Id.

As of July 9, 2020, the date on which the petitioner executed his third affidavit, he explained that "[o]n good days, [his] right should injury does not [a]ffect [him] much, [but] on bad days [he] ha[s] a sore shoulder, but [he] live[s] with it." Pet. Ex. 14 at ¶ 8.

III. EXPERT REPORTS

A. Petitioner's Expert, Dr. G. Russell Huffman

1. Background and Qualifications

Dr. Huffman is a shoulder and elbow surgeon and an Associate Professor of Orthopedic Surgery and Director of the Shoulder and Elbow Surgery Fellowship at the University of Pennsylvania Medical Center. Pet. Ex. 11 at 1; Pet. Ex. 12 at 1. Dr. Huffman earned his M.D. at Duke University School of Medicine, completed his surgical internship and orthopaedic surgery residency at the University of California, San Francisco, and completed shoulder and elbow fellowships at the University of Southern California and Mayo Clinic. Pet. Ex. 12 at 1. Dr. Huffman "oversee[s] 3,000 patient office visits a year and perform[s] over 450 surgeries per year." Pet. Ex. 11 at 1. He has authored over 100 publications and lectured nationally and internationally. Id. He researches shoulder and elbow issues and has diagnosed and treated patients with SIRVA for over eight years. Id. Dr. Huffman is currently investigating a SIRVA protocol at the University of Pennsylvania. Id.

2. Opinion

Dr. Huffman opined that "within a reasonable degree of medical certainty," petitioner developed a SIRVA injury immediately after vaccination. Pet. Ex. 11 at 4.

Citing Ryan,[4] Dr. Huffman explained that

> a vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following . . .
>
> - No prior history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration;
> - Pain occurs within the specified time-frame;
> - Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
> - No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Pet. Ex. 11 at 3 (citing Pet. Ex. 28 at 5). He opined that petitioner meets all of these criteria. Id. at 4. He added that Ryan expanded SIRVA to include "conditions that cause a 'prolonged restriction of [shoulder] function.'" Id. at 3 (quoting Pet. Ex. 28 at 7).

Dr. Huffman found no evidence that petitioner had a shoulder injury prior to his vaccination in October 2014. Pet. Ex. 11 at 3. Based on petitioner's history and treatment, Dr.

[4] Tom Ryan, Injection-Related Work Grp., Dep't of Health & Hum. Servs., 2011 Institute of Medicine (IOM) Report Generated Proposals for Updates to the Vaccine Injury Table (VIT) (2011).

Huffman found a temporal relationship between petitioner's October 15, 2014 vaccination and his shoulder injury. Id. He found petitioner's pain began immediately after vaccination. Id. at 4.

B. Petitioner's Expert, Dr. Marko Bodor

1. Background and Qualifications

Dr. Bodor is "a board-certified Physical Medicine and Rehabilitation specialist with subspecialty board certifications in Sports Medicine and Pain Medicine." Pet. Ex. 15 at 1. Dr. Bodor received his M.D. from the University of Cincinnati, and then completed a surgical internship at the University of California, San Diego and a physical medicine and rehabilitation residency at the University of Michigan. Pet. Ex. 16 at 1. He currently holds various positions including Voluntary Assistant Professor in the Department of Neurological Surgery at the University of California, San Francisco and in the Department of Physical Medicine and Rehabilitation at the University of California, Davis. Id. Dr. Bodor also runs his own private practice where he sees various patients with SIRVA injuries. Id.; Pet. Ex. 15 at 1. He has authored or co-authored over 30 publications, given more than 30 lectures and presentations, and serves on various professional publications and organizations. Pet. Ex. 16 at 2-5, 7-9.

2. Opinion

Dr. Bodor opined that petitioner suffered a SIRVA injury to his right shoulder at the time of his flu vaccination on October 15, 2014. Pet. Ex. 15 at 3. Before reaching his opinions, Dr. Bodor reviewed petitioner's medical records and affidavits and cited supporting medical literature. Id. at 1-2, 4.

Dr. Bodor opined that petitioner's flu vaccination was administered too high in his shoulder, demonstrated by documentation from Jeremiah Noggle, FNP, describing the shot as given "2 fingerbreadths below the acromion process/proper injection site." Pet. Ex. 15 at 2 (quoting Pet. Ex. 3 at 1). Dr. Bodor, citing Bodor and Montalvo,[5] explained that petitioner's vaccination was administered within the region of the subdeltoid bursa. Id.

Bodor and Montalvo examined two patients with shoulder pain and weakness following vaccination and hypothesized that the "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet. Ex. 17 at 1-2. After examining the two patients along with 21 other volunteers, they "defined the subdeltoid bursa as being located in the potential space between the deltoid muscle and supraspinatus tendon extending from the acromion to the insertion of the supraspinatus tendon at the anatomical neck of the humerus." Id. at 2. "Given that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule," as well as "adhesive capsulitis." Id. Because multiple structures within the shoulder were involved in both patients, Bodor and Montalvo found this suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3. The authors concluded that "the diagnosis of

[5] Marko Bodor & Enoch Montalvo, Vaccination-Related Shoulder Dysfunction, 25 Vaccine 585 (2007).

vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection." Id.

Dr. Bodor also cited Atanasoff et al.,[6] where the authors identified thirteen cases where "vaccine administration led to significant shoulder pain and dysfunction." Pet. Ex. 18 at 1-2. Based on their investigation, the authors proposed that "the unintentional injection of antigenic material into synovial tissues result[s] in an immune-mediated inflammatory reaction." Id. at 1. "[T]he rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. The authors noted that some of their MRI findings "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation. Other findings such as fluid collections, localized tendon inflammation, and bursitis are more consistent with the vaccine needle over-penetration mechanism." Id. at 3-4.

Dr. Bodor noted that prior to the vaccination at issue, petitioner had no history of right shoulder pain or dysfunction. Pet. Ex. 15 at 2. After vaccination, petitioner immediately developed pain. Id. Given petitioner's age, Dr. Bodor found osteoarthritis and rotator cuff disease "very rare." Id. at 2-3. Thus, he concluded that "[petitioner's] findings are most consistent with a chronic inflammatory problem such as adhesive capsulitis or SIRVA." Id. at 3.

Dr. Bodor addressed petitioner's "normal examinations" with Mr. Noggle on November 6 and Dr. Karen Barton on November 17, 2014. Pet. Ex. 15 at 3. On November 6, 2014, petitioner presented to Mr. Noggle for shoulder pain from a flu vaccination one month prior. Pet. Ex. 3 at 1. Mr. Noggle found "normal active [range of motion]" and "[n]o tenderness or induration with palpation of injection site." Id. Petitioner presented to Dr. Barton on November 17, 2014 with complaints of "[r]ight lateral shoulder pain acute onset since flu vaccine 6 weeks ago." Pet. Ex. 2 at 7. Dr. Barton's musculoskeletal exam of petitioner was normal and petitioner's range of motion exam showed no pain, crepitation, or contracture. Id. at 9. Dr. Bodor argued neither "examiner[] has expertise in musculoskeletal disorders" and "their examinations were non-specific and very brief." Pet. Ex. 15 at 3. He suspected that neither examiner noticed key findings of loss of range of motion, pain, and weakness, and thus argued these comments should not be relied on in evaluating petitioner's claim. Id.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

[6] S. Atanasoff et al., Shoulder Injury Related to Vaccine Administration (SIRVA), 28 Vaccine 8049 (2010).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health &

Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner's claim predates the inclusion of SIRVA on the Table, he must prove his claim by showing that his injury was caused-in-fact by the vaccination in question. § 11(c)(1)(C)(ii). To do so, petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35

F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The mechanism for a SIRVA injury is well described in medical literature filed in this case. In summary, the Atanasoff authors' proposed mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Pet. Ex. 18 at 1. They found "rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. Bodor and Montalvo proposed that a "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet. Ex. 17 at 1-2. They found multiple structures within the shoulder involved, which suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3.

Further, when proposing the addition of SIRVA to the Vaccine Table, respondent discussed the mechanism by which this injury is caused. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015).

The undersigned takes judicial notice of the fact that respondent has added SIRVA after receipt of an intramuscularly administered flu vaccine to the Table. Such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first Althen prong. See Doe 21 v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 178, 193 (2009), rev'd on other grounds, 527 F. App'x. 875 (Fed. Cir. 2013).

Additionally, the undersigned notes that, prior to the adoption of the revised Table, which is effective for petitions filed on March 21, 2017 and later, respondent conceded entitlement in numerous SIRVA cases alleging causation by an intramuscularly administered flu vaccine. See, e.g., Cothern v. Sec'y of Health & Hum. Servs., No. 14-574V, 2014 WL 6609687 (Fed. Cl. Spec. Mstr. Oct. 15, 2014); MacLaughlin v. Sec'y of Health & Hum. Servs., No. 17-57V, 2018 WL 3030269 (Fed. Cl. Spec. Mstr. Mar. 16, 2018). Even after the revised Table became effective, respondent continued to concede cases which may not have met the Table criteria, but in which respondent, nevertheless, believed causation had been established. See, e.g., Buras v. Sec'y of Health & Hum. Servs., No. 17-1012V, 2018 WL 4042194 (Fed. Cl. Spec. Mstr. Apr. 13, 2018).

Moreover, petitioner submitted the expert opinions of Dr. Huffman and Dr. Bodor who provided a sound and reliable medical and scientific theory of causation supported by medical literature. Dr. Bodor explained that the injection was administered too high in the shoulder into the subdeltoid bursa. Pet. Ex. 15 at 2. Like petitioner, the patients in Bodor and Montalvo were

administered a vaccine into the subdeltoid bursa, which "caus[ed] a robust local immune and inflammatory response." Pet. Ex. 17 at 1-2; see also Pet. Ex. 15 at 2. Bodor and Montalvo found multiple structures within the shoulder to be involved which suggested "a primary inflammatory etiology." Pet. Ex. 17 at 3.

The undersigned finds petitioner has provided by preponderant evidence a sound and reliable theory that the flu vaccine administered intramuscularly can cause a SIRVA, and therefore, petitioner has satisfied the first Althen prong.

B. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is preponderant evidence in the record to support a logical sequence of cause and effect showing the October 15, 2014 flu vaccination to be the cause of petitioner's right shoulder pain. See Althen, 418 F.3d at 1278. First, Dr. Huffman's report and the medical literature provide a framework for evaluating whether petitioner's claim is consistent with SIRVA. The criteria are as follows:

> a vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following . . .
>
> - No prior history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration;
> - Pain occurs within the specified time-frame;
> - Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
> - No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Pet. Ex. 11 at 3 (citing Pet. Ex. 28 at 5). A vaccinee is considered to have suffered from a SIRVA injury if he manifests all four of the above criteria. Id.

1. Prior Condition

Based upon a review of the record as a whole, including the medical records, affidavits, and expert reports, the undersigned finds there is no evidence that petitioner experienced any issues with his right shoulder prior to vaccination.

2. Pain Onset

Respondent argues that Dr. Huffman summarily concluded that petitioner's shoulder pain began within 48 hours based on petitioner's statements. Resp. Response at 10 n.12. Petitioner argues his pain began immediately and "clearly within 48 hours of the vaccination." Pet. Mot. at 2. Petitioner's experts also opined that petitioner's right shoulder began "immediately" after vaccination and "within the requisite 48-hour window." Pet. Ex. 11 at 4; see also Pet. Ex. 15 at 2.

Based on the evidence, the undersigned finds petitioner's pain began within 48 hours of vaccination. The earliest in time document regarding onset is petitioner's visit to Jeremiah Noggle, FNP on November 6, 2014, three weeks and one day after vaccination. Petitioner complained of "[s]houlder pain from shot" with "shooting pain/weakness/decreased [range of motion]" in his right deltoid. Pet. Ex. 3 at 1. Mr. Noggle added that petitioner "pointed to the area where the shot was given in the right deltoid 2 fingerbrea[d]ths below the [acromion] process/proper injection site." Id.

On November 17, 2014, petitioner was seen by Dr. Barton for "[r]ight lateral shoulder pain acute onset since flu vaccine 6 weeks ago." Pet. Ex. 2 at 7. Petitioner stated the "[p]ain occurred within seconds of injection." Id.

On November 21, 2014, petitioner had an initial physical therapy assessment for right shoulder pain at Robinson Rehab Center & Sport Clinic. Pet. Ex. 1 at 4. At his November 24, 2014 visit, his physical therapist documented that petitioner's right shoulder has hurt since his vaccination. Id. at 3.

Additionally, petitioner averred that "[a]lmost immediately after receiving the injection for the [flu] vaccination, [he] began to suffer pain in [his] right shoulder, making it difficult to move the shoulder and use [his] right arm." Pet. Ex. 13 at ¶ 6.

Based on the contemporaneous medical records and affidavits, the undersigned finds the onset of petitioner's shoulder pain began immediately after vaccination, and well within two days or 48 hours of his October 2014 vaccination.

3. Scope of Pain and Limited Range of Motion

Based on the petitioner's affidavits and medical records, petitioner's vaccine-related symptoms were limited to his right shoulder. Petitioner's November 2014 visits document pain in petitioner's right shoulder. Pet. Ex. 2 at 7; Pet. Ex. 3 at 1. Records from petitioner's physical therapy sessions also document right shoulder pain. Pet. Ex. 1 at 2-3. On December 21, 2016, petitioner was seen by Dr. Edward Scott and was diagnosed with shoulder tendonitis. Pet. Ex. 7 at 1. Although the record does not specify which shoulder, it does reflect that petitioner was referred to physical therapy to evaluate and treat for improved range of motion. Id. at 3. On January 26, 2017, petitioner was seen at University Hospitals Rehabilitation Services for physical therapy, where his diagnosis was shoulder tendonitis. Pet. Ex. 9 at 1. Throughout the physical therapy records, petitioner's shoulder pain is continuously noted to be in his right shoulder and an examination noted decreased range of motion in the right shoulder. See id. at 1-3. Relative to the right shoulder injury alleged in the petition, there is no indication that petitioner experienced pain or limited range of motion in any area other than his right shoulder.

4. Other Condition or Abnormality

Drs. Huffman and Bodor identify no other condition or abnormality to explain petitioner's symptoms. Pet. Ex. 11 at 4; Pet. Ex. 15 at 2-3.

The undersigned finds there is nothing in the record that points to another condition or abnormality as the cause of petitioner's symptoms.

In conclusion, petitioner's injury meets the criteria for SIRVA and petitioner's clinical course mirrors a typical SIRVA injury. Therefore, the undersigned finds petitioner has proven by preponderant evidence a logical sequence of cause and effect and has satisfied the second Althen prong.

C. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." De Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

As stated above, the undersigned finds the onset of petitioner's right shoulder pain occurred within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. See Althen, 418 F.3d at 1278.

The undersigned finds the evidence discussed in this Ruling qualifies as preponderant evidence to show the flu vaccine caused petitioner's shoulder injury within the time frame required. The temporal association is appropriate given the mechanism of injury. Thus, petitioner has satisfied the third Althen prong.

VI. CONCLUSION

Based on the record as a whole and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish petitioner's October 15, 2014 flu vaccination caused his right shoulder pain and limited range of motion. Thus, the undersigned finds that petitioner has established by preponderant evidence that he is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master